

ROGER KELVIN Ideas & Insights | Cosmetics



**REGULATORY CHALLENGES IN
COSMETICS INDUSTRY**

ROGER KELVIN PARTNERS

REGULATORY CHALLENGES IN COSMETICS INDUSTRY

Cosmetics is a dynamic industry, with ever increasing number of products launched throughout the year and increasing competition, the challenge to innovate and roll out new products puts significant pressure on companies to keep up with global regulations. While large cosmetic companies have full scale in house regulatory teams and regional offices to manage the regulatory requirements, small to mid- size cosmetic companies struggle to keep up with commercial plans while being compliant. Key regulatory challenges faced by cosmetic companies include,

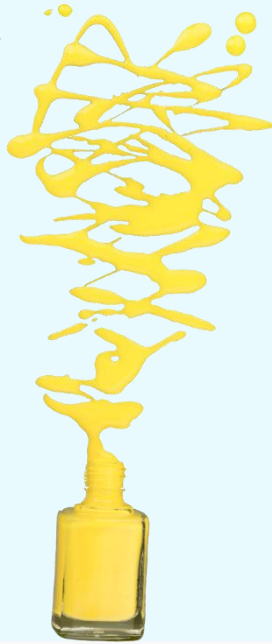
LACK OF GLOBAL REGULATORY KNOWLEDGE

World's top 10 global cosmetic markets are in different continents, each with their unique regulations and process for importation. With heterogenous population and culture, country specific regulations and control over ingredients and label add on to the regulatory complexity with additional cost of compliance. Often commercial plans for new products are dropped in the board rooms when regulatory challenges are presented for different markets of interest. Therefore, it is important for companies to gain a comprehensive understanding of regulations in all the

countries of interest to integrate within their commercial plan.

This will allow better time for product development and launch factoring the regulatory bottlenecks that may potentially affect timelines.

60% OF TIME OF REGULATORY PROFESSIONALS IS USED IN MAINTENANCE ACTIVITIES INSTEAD OF GROWTH ACTIVITIES



KEEPING UP WITH PACE OF NEW PRODUCT DEVELOPMENT AND LAUNCH

Changing consumer demands constant innovation from cosmetic product manufacturers and suppliers. Country specific regulatory requirements often present themselves as rate limiting steps through the lifecycle of product from conceptualization, formulation to product launch. Seeking timely approvals for marketing the product, obtaining necessary clearances are critical to supply products in shelves to maximize commercial benefits. The

regulatory professionals within the cosmetic companies need understand these business sensitivities. Compared to tradition regulatory functions within pharmaceutical industry, cosmetic industry is driven by significantly different business dynamics.

COORDINATING WITH MANUFACTURERS AND 3RD PARTY SUPPLIERS

Cosmetic companies have bouquet of products for different applications such as personal care, home care, fabrics, artifacts, grooming and other categories of products. Often companies source their raw material or private labeled finished products from 3rd party suppliers and manufacturers. As regulations demand, a significant amount of technical information required as part of Product Information File, SDS/ MSDS or label comes from these manufacturers. Depending on number of SKUs, collecting and managing the information from these manufacturers determines the effort required to keep the information up to date for any regulatory submissions. Coupled with need for new product registration, maintenance of existing licenses, procuring and maintaining the data is both time consuming and challenging since often manufacturers are reluctant in sharing the information due to proprietary nature. It is important for companies to set right expectations in the beginning with the suppliers regarding the information requirements and put necessary agreements in

place to secure suppliers' interests.

ON-GROUND PRESENCE IN COUNTRIES OF INTEREST

Country regulations require a qualified person to be responsible for commercialization of cosmetic products in the country. The everyday regulatory operations management does not demand high time commitment; however, it is a critical process to meet regional compliance needs to stay in market and avoid unfortunate legal and financial burdens. Therefore, companies cannot justify hiring a regional regulatory person or business operations due to the commercial opportunity versus cost of operations in the country.



FINDING DYNAMIC REGULATORY PROFESSIONALS TO MANAGE GLOBAL NEEDS

Cosmetic industry is highly consumer driven and demands individuals working in the cosmetic industry to adapt to consumer requirements, implement proactive and reactive strategies, consistently innovate and respond to market demands. Companies often face challenges in finding the right regulatory professionals who fit with the industry mindset? Regulatory professionals managing cosmetic products need to learn from methods applied by peers from other departments to keep up with fast paced environment. This may include adapting harmonized strategies, use of tools and methods to accelerate processes, identifying regulatory risks and costs to recommend optimum strategies to time product launches.

SUMMARY

Companies across industry and regions are adapting mix of strategies to align with their business needs while staying compliance. As often it is not practical for small to mid-size companies to have full scale regulatory teams or operations team in each country they market their products in; companies seek external support from regional consultants or regulatory companies with global presence to overcome the regulatory challenges while they retain their focus on commercial expansion. A hybrid model with part inhouse regulatory team for key markets coupled with regulatory partners continues to be preferred *modus operandi* for such companies.

COST OF COMPLIANCE – LABELING AND OTHERS

Cosmetic industry is all about aesthetics. It takes years to build the brand personality and create branding guidelines that consumers associate with including the product packaging and design. Since most companies plan multi-country launch of products at about same time, brand consistency becomes significant parameter that it can influence a go, no-go decision. Country specific regulations demand certain additional information on labels (primary and secondary packaging) based on regional laws, cultural and language requirements that in most cases It is difficult for cosmetic companies to implement a different packaging for different country. It doesn't make a profitable proposition. Identifying risk associated with non-compliance and minimal approach to steer through country specific regulations is key for regulatory teams in cosmetic industry to help companies achieve their business objectives.